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SUBJECT: PHARMA, IPR AND MARKET ACCESS TOP TIFA AGENDA

REF: A) Hanoi 1027 (Vietnam Endorses Economic Liberalization);  
B) GSP Phrma Submission, August 4, 2008;  
C) Hanoi 194 (Vietnam Should Remain on the 301 Watch List);  
D) Hanoi 738 ("Focus on U.S. Business Concerns");  
E) Hanoi 243 ("Vietnam Trade in 2007");  
F) Hanoi 451 (Vietnam Opens the Door Wider on Distribution)

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¶1. (U) This cable is sensitive but unclassified. For official use only, not for dissemination outside USG channels or posting on the internet.

¶2. (U) SUMMARY. The United States and Vietnam held the latest round of discussions under the Trade and Investment Framework Agreement (TIFA) in Hanoi during August 25-28. The TIFA agenda included expanding market access for U.S. beef, pharmaceuticals and media products, and strengthening Vietnam's IPR regime, among other issues. Vietnam raised market access for its fruits, concerns about the extension of the U.S. import monitoring program for apparel from Vietnam, and its pending application for eligibility for the Generalized System of Preferences (GSP). The TIFA, just over a year old, has proven to be one of the most useful mechanisms at our disposal to address and resolve common investment and trade concerns and to develop new initiatives to further deepen bilateral ties. END SUMMARY.

¶3. (U) Vietnam and the United States held the fifth meeting in an ongoing series of discussions under the TIFA since its inception in 2007 (two at the ministerial level in the United States and three at the senior official level in Hanoi) from August 25-28. The U.S. team was led by Deputy USTR John Veroneau (REF A) and included USTR Southeast Asia Director David Bisbee and Embassy Hanoi Economic and Commercial officers. The Vietnamese TIFA side was led by the Office of the Government and the Ministry of Industry and Trade, and included the ministries of Foreign Affairs, Planning and Investment, and Health, and the National Office of Intellectual Property. Some of the discussions also included the National Assembly.

OPENING A DOOR TO U.S. PHARMACEUTICALS  
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¶4. (U) A series of meetings with the Ministry of Health (MOH) during these TIFA discussions and the previous round in May showed the possibility of breakthroughs in simplifying regulations governing data exclusivity and clinical trials (REF B). In May, MOH Officials had acknowledged that GVN policy on both issues had caused confusion among international pharmaceutical firms, and expressed an interest in improving implementation and ensuring Vietnamese policy is in line with international standards. At the August 26 meeting, the MOH presented us with a new draft for clinical trials and asked us

to comment on it and share it with the pharmaceutical industry for comments, which post and USTR have done.

15. (SBU) On data exclusivity, the Director General of the MOH's Drug Administration (DAV) expressed a willingness to consider making changes to DAV's process for granting data exclusivity, which, if implemented, would provide the protection that the pharmaceutical industry seeks, as well as relieve the overwhelmed DAV adjudicators from having to examine every detail in new drug applications -- a practice so cumbersome that it has virtually paralyzed the application process. The Deputy Director General of the National Office of Intellectual Property (NOIP), Phi Anh, agreed that this could be a good solution, and both offices will now submit the proposal up their chains of command.

16. (U) At the meeting with the MOH, the two sides also discussed the need for a roadmap to clarify pharmaceutical industry access to the Vietnamese market. [Vietnam excluded pharmaceutical products from its WTO distribution services commitments, creating considerable ambiguity regarding future opportunities for U.S. pharmaceutical firms.] In January 2009, foreign firms will be able to exercise import rights for pharmaceutical products. Under current Vietnamese trading rights regulations this would include extending importation privileges to foreign importers operating inside Vietnam. For pharmaceutical firms to take advantage of this phase-in they would need to establish a legal entity in Vietnam which would serve as the importer and initial link to the current distribution network.

17. (U) Currently, most pharmaceutical firms not engaged in production are registered in Vietnam as representative offices and, as such, are not permitted to carry out commercial activities. Some of these firms have expressed an interest in transitioning their representative offices into branch operations, but Vietnamese authorities are having difficulty coming up with a way to regulate the scope of operations of branches, particularly how to keep them

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from engaging in restricted activities (key concerns being distribution and to some degree the activity known in the trade as 'detailing' or promoting products through direct outreach to physicians and practitioners). The two sides promised to continue discussions, and the Mission will monitor the situation closely, as the import rights implementation date approaches.

#### IPR ISSUES ON THE TABLE

18. (SBU) NOIP Deputy Director General Phi Anh chaired a meeting of the TIFA IPR working group, which included officials from NOIP, the ministries of Industry and Trade (MOIT), Justice, Information and Communication, Culture, and Health. The two sides continued their ongoing discussion on creating a work plan to address key deficiencies in Vietnam's administrative enforcement system as identified by U.S. and local rights-holders and based on extensive engagement by Post. The U.S. side raised concerns by U.S. book publishers and music and film producers about the significant hurdles they face in entering the Vietnamese market because of restrictive regulations and weak enforcement of copyright protections. The U.S. side also raised the issue of Ephim.com, a geo-restricted Vietnamese internet site that offers pirated U.S. media content and is hosted by FPT, Vietnam's largest privately owned ISP. The GVN side said it would look into the matter.

#### IPR ENFORCEMENT AND LEGISLATION

19. (U) The TIFA IPR working group committed earlier this year to examine the primary obstacles in Vietnam for rights-holders seeking IPR enforcement, and review which information would be useful in facilitating enforcement cooperation. Both sides agreed on the need to update and revise the Embassy Hanoi-created web-based "IPR Tool Kit," and DDG Anh said that his office would seek U.S. technical assistance to update the Toolkit. One of the issues discussed earlier this year was the complaint by rights-holders that a cap on administrative fines levied for IP piracy due to a conflict between laws. Vietnam took steps to address this conflict and during the

meeting provided an update on newly issued Ordinance Number 4/2008, which clarified for GVN administrative agencies that the fines in the IP law are to be applied in cases of IP violations.

¶10. (U) As part of the IPR Toolkit enhancement exercise, USTR Southeast Asia Director David Bisbee asked if the NOIP could produce a list of all the GVN agencies with administrative authority over IP issues, with specific contact information and a detailed list of procedures and formalities required by each agency for administrative action. Such information would be useful for U.S. rights holders and would help them navigate the confusing set of agencies responsible for IP enforcement under Vietnam's administrative system. DDG Anh said that he aimed for a "one-door" policy when it comes to IPR issues.

¶11. (U) Bisbee said the United States recognizes Vietnam's progress in the area of IP protection and, with continued work by Vietnam, hopes the USG can acknowledge this progress during the next Special 301 Review in February 2009. He suggested that a "roadmap" could be a good way for NOIP to prepare for the next review. DDG Anh asked the U.S. side to consult with NOIP in advance of the next 301 Review to resolve misunderstandings or correct discrepancies.

¶12. (U) The U.S. side also encouraged the GVN to join the World Intellectual Property Organization (WIPO) treaties, saying it would reaffirm Vietnam's commitment to IP protections. The U.S. side pointed out that U.S. industry is very supportive of Vietnam's progress and, in its view, Vietnam has already completed much of the necessary work to implement the treaties. Vietnam would be among the first countries in Southeast Asia -- and the first developing country in the region -- to actually implement the WIPO treaties. Bisbee urged the GVN to step up its enforcement of IP over the coming months, particularly in the digital environment. He reemphasized the United States' willingness to deepen cooperation with the Ministry of Justice (MOJ) as it proceeds with the long-promised revision of Vietnam's criminal code provisions related to IP. MOJ is currently working on the latest draft of the IP amendments, and indicated in the meeting that it hopes to have a final version passed by the National Assembly in November.

#### BEEF AND FRUIT ACCESS

¶13. (SBU) The U.S. side asked the Vietnamese to identify which specific concerns were holding back full market access for U.S. beef

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imports. The GVN officials told us that they would be in a position to make a decision on granting market access to live cattle and beef from animals older than 30 months after it concludes its ongoing risk assessment. On September 15, Vietnam presented a preliminary and inconclusive risk assessment that calls for further data gathering, which the relevant USG agencies are examining.

¶14. (U) The GVN representatives said that they were eager to gain market access for longan, lychee and rambutan fruits (dragonfruit exports to the U.S. were approved on July 29, 2008). They said that an Agriculture Ministry (MARD) delegation would visit the U.S. in October to discuss both the beef and fruit issues.

GSP  
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¶15. (SBU) At all levels, GVN officials reiterated their interest in getting GSP approval before the end of the year. The U.S. team urged the Vietnamese to pay close attention to the public comments that were submitted during the process, and address particular areas of concern. The U.S. side noted that labor, for instance, "will always come up in the trade context, so this is a great opportunity to address it and do a roadmap to move forward." OOG Minister Phuc assured Veroneau in an August 26 meeting that Vietnam would make efforts to address the labor concerns.

#### APPAREL IMPORTS AND MARKET ECONOMY

¶16. (U) Vietnamese officials also expressed alarm that the Import Monitoring Program (IMP) for textile and apparel Vietnamese exports, which expires in December of this year, may be extended. The U.S. side stated that the Administration has no plans to extend the program, but acknowledged that this did not foreclose the possibility of a congressionally-mandated extension. Vietnam and the United States also discussed the way forward on the bilateral working group to review trade remedies and market economy status, and the Department of Commerce's proposal to have the first round of meetings on December 11-12, 2008 in Vietnam.

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¶17. (SBU) The Vietnamese, up to the Prime Minister, reaffirmed their support for the Bilateral Investment Treaty. Their team, led by the Planning and Investment Ministry (MPI), promised to share possible dates with us in order to schedule the first round of negotiations. Since then, however, the MPI negotiators have not committed to negotiation dates. Post is following up with them and other GVN officials to commit to a first round timetable.

#### IMPORT LICENSING AND OTHER AUTOMOTIVE CONCERNS

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¶18. (U) Faced with a trade deficit that has reached a record \$16 billion up to August, Vietnam has tried several ways to curb import demand. One of those has been the institution of an "automatic" import licensing scheme that requires importers to apply for a permit for imports, showing proof of payment, among other things. The scheme, which has yet to be put into effect, would be burdensome and costly, according to foreign automakers and others in the private sector. During the TIFA meetings, Industry and Trade Ministry (MOIT) officials said that they only sought to collect information in order to anticipate their foreign reserve needs, and assured us that no license would ever be turned down. Relevant U.S. agencies are currently reviewing the new regime and developing a strategy for engagement.

#### LUXURY TAXATION ON CARS AND LIQUOR

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¶19. (U) Another concern from the automakers is the Special Consumption Tax (SCT or luxury tax) proposal under consideration by the GVN. On automobiles, the tax regime would focus on engine size rather than capacity, as is the case now, hitting U.S. large engine manufacturers hardest. (REF D) More problematic, the Ministry of Finance, which prepared the draft SCT law, is seeking to accelerate the implementation date of these changes from 2010 to 2009, which would not allow the carmakers sufficient time to adjust their production lines.

¶20. (U) Embassy Hanoi, within the TIFA discussions and on other occasions, asked the National Assembly, the MOIT and the Ministry of Finance (MOF) to consider the automakers' concerns as well as the

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overall implications of the rushed-in taxes on the country's business climate. On September 9, the MOIT proposed a compromise that would reduce the tax burden on larger engine cars and reset the implementation date back to 2010, although it is not clear whether other concerned Vietnamese government agencies will agree to this position. Post will continue to follow up on this issue.

¶21. (U) The SCT draft would also harmonize luxury tax rates between domestic and foreign liquor (spirits, wine and beer), in line with Vietnam's WTO commitments. Embassy Hanoi has met with the industry, which has been receptive of the draft. During the TIFA discussions, the U.S. side noted, however, the irony of the GVN's justification of the 2010 implementation date for luxury taxes on liquor ("to allow more time for our domestic industry to adjust") with the MOF's refusal to consider doing the same for the automotive industry.

#### DISTRIBUTION, ASSOCIATIONS AND REGIONAL DISSONANCE

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¶22. (U) All of the issues described above will continue to form part of the bilateral trade and investment discussion for the foreseeable future. During this and previous TIFA meetings the U.S. has also raised our interest in engaging in other key issues, such as freeing Vietnam's regulations on associations (trade and otherwise), addressing complaints from the provinces that trade regulations are sometimes interpreted more restrictively at the regional level than by the central government (Septel), and our interest in ensuring a smooth opening of the distribution sector to fully-foreign owned firms in 2009.

COMMENT: THE TIFA PROVING ITS WORTH  
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¶23. (SBU) The Vietnam-United States trade and investment relationship is moving at a very fast pace. Bilateral trade this year has increased by 25% up to July from the same period in 2007, which was a banner year itself (REF E). Our exports to Vietnam this year are up by 104% over the same period in 2007, while Vietnamese exports are down slightly by 12%. U.S.-committed investment this year alone accounts for half of all U.S. investment over the last 10 years. By virtue of its flexibility, the TIFA has been one of our most useful tools in dealing with issues raised by this burgeoning relationship as they arise, whether in fixing troublesome distribution sector rule (REF F), IPR piracy or investment-related fixes.

¶24. (U) This telegram was coordinated with the office of the USTR.

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